

REMARKS

Applicant respectfully requests reconsideration of the above-identified Patent Application in light of the Amendment and Remarks.

This Amendment is filed in response to the Restriction Requirement set forth in the 11.5.07 Office Action.

Status of Petition to Correct Filing Receipt

Applicant previously filed a Petition to Correct Filing Receipt on March 13, 2007, which attached the requisite proof (stamped postcard) of filing the instant application on October 14, 2005, not May 25, 2006. A copy of the March 13, 2007 Petition to Correct Filing Receipt is attached as Exhibit A. Upon receipt of the 10.5.07 Office Action, Applicant noted that the PTOL-90A cover sheet attached to the 11.5.07 Office Action continued to list 5.25.06 as the filing date of the instant application. Applicant respectfully requests correction of the filing date of the instant application pursuant to the 3.13.07 Petition.

Amendment Of The Claims

At page 2 of the 11.5.07 Office Action, the Examiner requested that "A new set of claims indicating the status of all the claims should be submitted." In response, Applicants have:

- (a) withdrawn claims directed to non-elected inventions;
- (b) amended claims 1, 3, 7-10, and 13 so as to conform with the Group II (medical device) invention identified in the 11.5.07 Office Action; and
- (c) added new claims 17-19 directed to the Group II (medical device) invention identified in the 11.5.07 Office Action.

Specification support for the above-listed new and amended claims is found at least as follows:

Support for “medical device” is found at at least paragraph 1 of the specification as filed.

Support for “blood” is found at at least paragraph 18 of the specification as filed.

Support for “test strip” is found at at least paragraph 18 of the specification as filed.

Support for “spreading” is found at at least paragraph 20 of the specification as filed.

Support for “a filtering layer” is found at at least paragraphs 26 and 34-35 of the specification as filed.

Support for “dry” is found at at least paragraph 44 of the specification as filed

Support for “enzyme” is found at at least paragraph 27 of the specification as filed.

Support for “buffered enzymatic color-imetric reagents” is found at at least paragraph 24 of the specification as filed.

Support for “means for reading...measurement” is found at at least paragraph 64 of the specification as filed.

Support for “means for storing...” is found at at least paragraph 58 of the specification as filed.

Support for “compound selected from the group consisting of gelatin and agarose” is found at at least paragraph 24 of the specification as filed.

Support for “electron mediator” is found at at least paragraph 30 of the specification as filed.

Support for “download” is found at at least paragraph 66 of the specification as filed.

Support for “fluid contact” is found at at least paragraph 22 of the specification as filed.

Support for “10kD” is found at at least paragraph 32 of the specification as filed.

Support for “water soluble” is found at at least paragraph 42 of the specification as filed.

Support for “pH 8.6” is found at at least paragraph 36 of the specification as filed.

It is noted that this Amendment is fully supported by the originally filed application and thus, no new matter has been added. For this reason, the Amendment should be entered.

Restriction Requirement

Claims 1, 3, 7-10, 13, and 17-19 are presented for examination, with claim 15 having been withdrawn hereby (without prejudice or disclaimer) and claims 2, 4-6, 11-12, 14 and 16 having been previously canceled (without prejudice or disclaimer).

In the November 5, 2007 Office Action, the Examiner indicated that restriction to one of the following so-called Inventions as indicated below would be required:

- Invention I: test element for determining the level of phenylalanine in a biological fluid: claims 1, 3, 7 and 8. In view of the instant claim amendments, it is Applicant’s view that the category of Invention I now includes pending claims 3, 7-10, and 17-19.
- Invention II: medical device adapted for the monitoring of blood levels of phenylalanine: claims 11, 12 and 16. In view of the instant claim amendments, it is Applicant’s view that the category of Invention II now includes pending claims 1, 3, 7-10, 13, and 17-19.
- Invention III: method for determining the presence or absence of phenylalanine in a biological sample: claim 15. In view of the instant claim amendments, it is Applicant’s view that the category of Invention III now includes withdrawn claim 15.

In response, applicants hereby elect so-called Invention II (claims 1, 3, 7-10, 13, and 17-19).

Of note, applicants specifically reserve the right to add generic claim(s) during the prosecution of the application. In addition, applicants specifically reserve the right to file divisional application(s) directed to any non-elected invention.


Finally, it is noted that this Amendment is fully supported by the originally filed application and thus, no new matter has been added. For this reason, the Amendment should be entered.

Applicant urges that this application is now in condition for allowance and earnestly solicits early and favorable action by the Examiner.

Early and favorable consideration on the merits is earnestly solicited.

Respectfully submitted,
GREENBERG TRAURIG, LLP

Dated: December 5, 2007

By: 
David M. Joyal
Registration No. 57,238

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Attorney Docket No.: 055142.010102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: SHUNNARAH, Richard, et al.

SERIAL NO.: 10/552,953

Group Art Unit: 1654

FILED: October 14, 2005

Examiner: Not Yet Assigned

FOR: MEDICAL DEVICE FOR MONITORING BLOOD PHENYLALANINE LEVELS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

PETITION TO CORRECT FILING RECEIPT

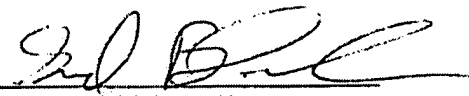
Sir:

Applicants respectfully request that the Filing Date set forth in the Filing Receipt, copy attached, be corrected. This application was filed on October 14, 2005, not May 25, 2006. See copy of post card, attached. Accordingly, correction is requested.

No fee is believed due from the filing of this Petition. If a fee is due, however, please deduct it from our Account No. 50-1561.

Dated: March 13, 2007

Respectfully submitted,

By: 
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Applicant (s): SHUNNARAH, R.

Serial No.: T/B/A

Docket No.: 55142.010102

Attorney: Eugene C. Rzucidlo

Title: MEDICAL DEVICE FOR MONITORING BLOOD
PHENYLALANINE LEVELS

Receipt is hereby acknowledged by return of this postal card properly stamped by the US PTO
for the above noted matter of the following:

1. Transmittal Form PTO 1390
2. Copy of International Application No. PCT/US04/011706 A2
3. Specification (17 pages)
4. Abstract (1 page)
5. Drawings (2 pages)
6. Copy of Int'l. Search Report
7. Supplemental Amendment (8 pages)
8. Unexecuted Declaration/Power of Attorney
9. Certificate Express Mail
10. Postcard receipt

Mailed: October 14, 2005 via Express Mail Label No. EV 570 899 346 US
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FROM: (PLEASE PRINT) 55142.010101 / Rzucidlo			TO: (PLEASE PRINT) Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		

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APPL NO.	FILING OR 371(c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLMS	IND CLMS
10/552,953	05/25/2006	1654	365	55142.010102	14	1

CONFIRMATION NO. 2493

32361

GREENBERG TRAURIG, LLP
 MET LIFE BUILDING
 200 PARK AVENUE
 NEW YORK, NY 10166

FILING RECEIPT



OC000000022555019

Date Mailed: 03/06/2007

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Richard D. Shunnarah, Atlanta, GA;
 Sheldon W. May, Atlanta, GA;
 Charlie D. Oldham, Marietta, GA;
 Veronica De Silva, Atlanta, GA;

Power of Attorney: The patent practitioners associated with Customer Number 32361.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US04/11706 04/15/2004
 which claims benefit of 60/462,887 04/15/2003

Foreign Applications

If Required, Foreign Filing License Granted: 02/17/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/552,953**

Projected Publication Date: 05/31/2007

Non-Publication Request: No

Early Publication Request: No

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**** SMALL ENTITY ******Title**

Medical device for monitoring blood phenylalanine levels

Preliminary Class

435

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted

under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/552,953	Richard D. Shunnarah	55142.010102
INTERNATIONAL APPLICATION NO.		
PCT/US04/11706		
I.A. FILING DATE	PRIORITY DATE	
04/15/2004	04/15/2003	

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CONFIRMATION NO. 2493

371 ACCEPTANCE LETTER



OC000000022555020

Date Mailed: 03/06/2007

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

<u>05/25/2006</u>	<u>05/25/2006</u>
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Indication of Small Entity Status
- Copy of the International Application filed on 10/14/2005.
- Copy of the International Search Report filed on 10/14/2005
- Preliminary Amendments filed on 10/14/2005
- Information Disclosure Statements filed on 06/13/2006
- Oath or Declaration filed on 05/25/2006
- Request for Immediate Examination filed on 10/14/2005
- U.S. Basic National Fees filed on 10/14/2005
- Priority Documents filed on 10/14/2005
- Specification filed on 10/14/2005
- Claims filed on 10/14/2005

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- Abstracts filed on 10/14/2005
- Drawings filed on 10/14/2005

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

KAREN R MCLEAN
Telephone: (703) 308-9140 EXT 214

PART 1 - ATTORNEY/APPLICANT COPY

FORM PCT/DO/EO/903 (371 Acceptance Notice)